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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,401	03/25/2005	Joanne J. Fillatti	16518.145	7282
28381 7590 07/31/2008 ARNOLD & PORTER LLP ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206				
EXAMINER				
MCILWAIN, ELIZABETH F				
ART UNIT		PAPER NUMBER		
1638				
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07/31/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/508,401

Applicant(s)

FILLATTI ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9-12,22,25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9-12,22,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed April 28, 2008 has been entered.

Claims 2, 7, 8, 13-21, 23, 24 and 27-72 are cancelled.

Claims 1, 3-6, 9-12, 22, 25 and 26 are currently amended.

Claims 1, 3-6, 9-12, 22, 25 and 26 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 9, 10 and 22, and claims 3-6, 11, 12, 25 and 26 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1, 9, 10 and 22, and claims 3-6, 11, 12, 25 and 26 are indefinite in the recitation of "a nucleic acid sequence that suppresses the expression" and "a nucleic acid that increases expression . . .", given that "suppresses" and "increases" are relative terms and it is unclear what the level of expression is being compared to, and it is further unclear as to what would be encompassed by the term "a nucleic acid that increases expression of beta-ketoacyl-ACP synthase IV".

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3-6, 9-12, 22, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the last office action. The claims are now drawn to a soybean seed having specified ranges of oleic acid, linoleic acid, linolenic acid and saturated fatty acids by weight, wherein said seeds comprise in their genome a nucleic acid that suppresses FAD2-1A comprising a fragment that is 95% identical to FAD2-1A intron that is at least 100 nucleotides in length and said genome further comprising a nucleic acid sequence that increases expression of beta-ketoacyl-ACP synthase IV. However, the specification does not disclose any soybean seeds having the claimed ranges of fatty acids prepared by any method, and the specification does not provide any guidance with regard to identifying and/or selecting sequences that are capable of increasing expression of beta-ketoacyl-ACP synthase IV.

3. Applicants' arguments filed April 28, 2008 have been fully considered but they are not persuasive. Applicants argue that the specification as well as data from post-filed co-pending application 11/376,328. However, applicants only point to constructs that produced seeds having 55-80% by weight oleic acid and 2 to 8% by weight saturated fatty acids that are disclosed in the later filed application. Applicants do not discuss where support can be found in the present specification. The Examiner maintains that the specification does not enable the claimed invention and the deficiencies of the present specification are not overcome by post-filing date information provided in a co-pending application.

4. Applicants further argue that the cited references do not teach unpredictability of the claimed invention, stating that DeLuca teaches a general unpredictability that is not related to the claimed invention and that this reference does not establish the state of the prior art, since it predates applicants filing date. Applicants also assert that the Voelker reference is not applicable given that applicants have “claimed a fatty acid profile consistent with that of the plants produced by Applicants according to the specification” and that arguments relating to active site geometry are not relevant given that the claims relate to silencing endogenous FAD2. Applicants further argue that they are not claiming a method. Yet, applicants finally argue that one of ordinary skill in the art would have the skill required to create a construct that suppresses endogenous FAD2-1A and increase KAS IV expression, and to transform a soybean plant to produce a seed having 55-80% by weight oleic acid and 2 to 8% by weight saturated fatty acids without undue experimentation.
5. The Examiner maintains that the unpredictability of producing seeds having specified ranges of fatty acids is well established, as evidenced by the cited references, and that the specification does NOT disclose plants having the claimed fatty acid profiles. The Examiner maintains that the arguments relating to the method of making the claimed seeds are relevant given that enablement requires that one skilled in the art would be able to make and use the claimed invention. Furthermore, the claims are product-by-process claims, as indicated by applicants argument that one of ordinary skill would be able to carry out the method steps required to make the claimed seeds. Finally, applicants argue that the sequence similarity of fatty acid modifying enzymes is not relevant. The Examiner responds that in view of the

amendment of the claims limiting them to non-coding intron sequences for gene expression, this argument is moot.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fehr et al (US Patent 5,714,670), as stated in the last office action, and given that a soybean seed would comprise in it's genome a nucleic acid of at least 100 nucleotides in length that is at least 95% identical to a soybean FAD2-1A intron, and a nucleic acid sequence encoding a beta-ketoacyl-ACP synthase IV, wherein expression of said endogenous gene would increase expression of this enzyme.

8. Applicants' arguments filed April 28, 2008 have been fully considered but they are not persuasive. Applicants argue that the amendment of the claims should overcome the rejection.

9. The Examiner maintains that the rejection is still proper given that the claim amendments recite characteristics that would be present in the prior art soybean seed.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/

Primary Examiner, Art Unit 1638